#### **REMARKS**

Claims 1-20 are pending. All claims stand rejected. Additionally, claim 5 is objected to due to an informality, and claim 14 is rejected under 35 U.S.C. §112 due to use of "said" prior to establishment of an antecedent. All claims stand rejected substantively.

The informality in claim 5 has been corrected in accordance with the Examiner's suggestion. Claim 14 has been corrected to recite said cannula rather than said lumen. The cannula has an antecedent in prior claims.

Claim 1 stands rejected under U.S.C. §102(b) as being anticipated by United States Patent No. 6,299,590 to Lüscher. Claim 12 stands rejected under U.S.C. §102(b) as being anticipated by United States Patent No. 6,099,550 to Yoon. Claims 1, 8-11 and 12-14 stand rejected under 35 U.S.C. §102(b) as being anticipated by United States Patent No. 5,275,614 to Haber et al. (Haber). Claims 2-4 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Lüscher as applied to claim one in view of United States Patent No. 6,626,917 to Craig. Claim 5 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Lüscher as applied to claim 1 in view of United States Patent No. 5,236,443 to Sontag. Claims 6 and 7 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Lüscher and Sontag further in view of Craig. Claims 15, 16 and 18 stand rejected under 35 U.S.C. §103(a) as being unpatentable over

United States Patent No. 5,569,270 to Weng and Lüscher. Claim 17 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Weng and Lüscher as applied to claim 16 in view of Craig. Claims 19 and 20 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Weng and Lüscher as applied to claim 15 in view of Haber. Two additional references are made of record but not considered pertinent.

Claim 1 has been amended to more explicitly avoid the prior art. Claim 8 has been amended to correct a typographical error. Reconsideration of the grounds of rejection is requested.

Applicant gratefully acknowledges the interview with the Examiner of March 15, 2007. In the interview, the undersigned pointed out particular limitations in Applicant's claims that are not disclosed in the art of record. Additionally, the undersigned pointed out that certain characterizations of the art of record, e.g., suggesting that particular references disclosed syringes, are not supported by the record. Particulars are discussed below. The undersigned also pointed out that the art of record did not disclose drawing a suture in to a needle. The Examiner agreed to consider recitations reflecting this difference.

### Overview of Response

Applicant will first briefly describe features of the present subject matter which provide for significant operational advantages. Applicant will relate

these features to specific recitations in the claims. Applicant will discuss the general nature of a syringe. Applicant's claims each recite a syringe, and a number of grounds of rejection take a position that a reference discloses a syringe. However, in a number of instances, that position is not supported by the record. Then Applicant will discuss the various rejections under subheadings below and how the claims recite features not disclosed in prior art applied under 35 U.S.C. §102(b) and how such features are not suggested by the art applied under 35 U.S.C. §103(a).

### Overview of the Preferred Embodiments

Applicant recites a hydrodynamic suturing instrument. Among the instrument's many capabilities are manipulating a suture which may have been anchored to a patient's bone at one end which also has a free end. In one surgical procedure, the free end of the suture needs to be moved through a layer of tissue. In order to accomplish this, the free end of the suture is placed at the opening of a needle. A syringe plunger, or piston, is drawn axially away from the needle. The suture and liquid are then drawn into a syringe barrel of the hydrodynamic suturing instrument. The free end of the suture is held in the syringe while the needle is inserted through tissue. The needle emerges at an opposite side of the tissue. The syringe is operated by moving the plunger toward the needle. The free end of the suture is expelled from the syringe barrel

along with liquid. This operation is described in Applicant's specification with respect to Figures 12A-12D.

Claim 1 recites, at lines 3-5, that a barrel has a capacity to receive a predetermined size and length of suture and sufficient fluid to draw the suture into the barrel and expel the suture from the barrel at a later time. The instrument further comprises an elongated cannulated suturing needle communicating with the barrel and having a distal end configured with a sharp point. The sharp point can be inserted through tissue, and the suture expelled therethrough. Claim 1 has been amended to even more explicitly recite a hydraulic path and a plunger mounted to act on the hydraulic path to draw the suture into the syringe. This recitation is supported in the specification at paragraph [0032].

The method of claim 15 recites providing an elongated needle including a distal end having a tip configured for passage with a suture through a tissue. A syringe is detachably connected to the needle's proximal end. A length of suture is selected and introduced into the needle as well as a quantity of liquid. The length of suture is expelled from the distal end of the needle by hydraulic force from a quantity of liquid in the syringe. In the illustration of Figure 12A, the suture has one end that is free and which is drawn into the distal end of the needle. The

other end of the suture is anchored. It is impossible to perform the recited method with a suture that is preloaded in the syringe.

### The Syringe

Applicant recites a syringe in his claims. The term "syringe" has an established meaning in the art. Therefore, recitation of a syringe is a recitation of specific structure. This specific structure must be present in any prior art that is relied on to demonstrate anticipation or to suggest obviousness of claimed apparatus.

At <a href="http://en.wikipedia.org/wiki/Syringe">http://en.wikipedia.org/wiki/Syringe</a>, a syringe is described as a device which performs a pumping function. An aperture which interfaces a syringe barrel with the outside world is both the inlet and the outlet for liquid. The definition states in part that a syringe can be described as:

A simple hand-powered piston pump consisting of a **plunger** that can be pulled and pushed along inside a cylindrical tube (the **barrel**), which has a small hole on one end, so it can suck liquid in and then squirt it out by the same hole. The word "syringe" came from the Greek  $\sigma u \rho i \gamma \xi =$  "tube".

When Applicant states at various points in the discussion below, that a reference does not disclose a syringe, it is because there is no disclosure of the above-described components.

## The Rejections Under 35 U.S.C. §102(b)

### 1. Lüscher

Claim 1 stands rejected under 35 U.S.C. §102(b) as being anticipated by Lüscher. Lüscher discloses a device which dispenses a thread-like implant material from a barrel and through a needle for implantation into issue. Lüscher points out at column 4, line 56 through column 5, line 6 that a syringe 30 having a casing 31 houses bobbin 10 on which a fiber 13 is wound. A free end of the fiber 13 is inserted into a tube 19 of a hollow needle 17. The plunger 32 is moved in a direction toward the outlet of the chamber 31. Fiber 13 is unwound from the bottom 10 as the fluid transports the fiber toward a distal opening 20 and then to the outside.

It should be noted that Lüscher does not disclose an assembly including suture material. At column 3, lines 11-24, Lüscher explains that the fiber 13 is an implant material suitable for bunching up when it is inserted in a location into issue. The fiber 13 can comprise autologous blood components such as a fibrin-thrombocyte fiber. Other suitable materials are inorganic gels. Lüscher does not disclose an assembly containing a fiber having a requirement of a minimum tensile strength suitable for holding an object in place. Lüscher specifically describes a characteristic that the fiber 13 needs to be capable of forming into a ball. This is not a characteristic of suture material.

More importantly, Applicant recites at claim 1, line 8, a mechanism for drawing suture material into a needle. Because of Applicant's recited structure, an apparatus is provided which of necessity has the capability of taking a loose end of a suture which is anchored at an opposite end and drawing the loose end into a syringe so that the suture may be carried through tissue by a needle. In the embodiments of Figures 1-4 and 6-7, Lüscher makes it impossible to draw a suture in to his chamber 8. The embodiment of Figures 1-4 comprises a check valve 5. The valve 5 permits liquid flow through the chamber 8 in only one direction. Lüscher can only expel fiber from his tube 17. In the embodiment of Figure 6, a pump 44 provides for fluid flow in only one direction. Since a limitation recited by Applicant is absent from the teachings of the reference, under MPEP §2131, an anticipation rejection may not be maintained.

In Lüscher's description of the embodiment of Figure 5, cited in the rejection, Lüscher only describes moving his plunger 32 "to the left" (column 5, line 3). Lüscher's Figure 5, must be rotated clockwise 90°, and it is seen that motion to the left refers to expelling liquid from the casing 31. Lüscher teaches an operation that is contrary to the operation performed by Applicant's recited apparatus. Additionally, the structure disclosed by Lüscher in the embodiment of Figure 5 is different from that recited by Applicant. It is due to this difference in structure that Lüscher's apparatus cannot draw an end of the non-suture fiber 13 into the tube 19.

As pointed out, for example, at column 1, line 58 to column 2, line 3, the sole purpose of Lüscher's device is to deposit implant fiber in a patient. A fiber 13 unwinds unidirectionally from a fiber bobbin 10 into a tube 19 of a hollow needle. The structure does not permit clearing the fiber 13 from the tube 19. In contradistinction, Applicant recites a hydraulic path to receive an incoming suture and a plunger to act on that path to draw in a suture. Lüscher only provides a hydraulic path that is occupied by a fiber to be expelled. The structure of Lüscher cannot receive a suture. Additionally, if Lüscher's plunger is operated to draw in a suture, it will also cause the non-suture fiber to go in the "wrong direction," with no particular provision being made to avoid fouling the operation of the fiber bobbin 10. Since Lüscher does not include an explicitly recited element of Applicant's claim 1, under MPEP §2131, Lüscher cannot service the basis for a rejection under 35 U.S.C. §102(b).

#### 2. Yoon

Claim 12 stands rejected under 35 U.S.C. §102(b) as being anticipated by Yoon. The rejection states that Yoon discloses a suturing instrument containing an elongate tubular member, and relatively movable jaws having openings therein, a syringe having a needle that extends through the elongated tubular member towards the jaws and which is capable of receiving a suture. It is

respectfully submitted that this characterization of Yoon is unsupported by the record.

Yoon does not disclose a suturing instrument. Yoon does not disclose a syringe. Yoon does not disclose an opening in a jaw. Yoon specifically points out at the column 2, lines 44-52 that, "the present invention is generally characterized in [sic] an instrument including a forceps unit for being positioned within an anatomical cavity and an operating channel defined in the instrument for permitting a movable member to be advanced through the instrument or for providing communication with that the anatomical cavity." Yoon points out at lines 28-41, for example, that the instrument 30 is moved to position the jaws 38 and 40 within an anatomical cavity. As saying, for example, the tubular outer member 34 may be moved axially in a first direction to bear against cams 70 and 72 in order to close the jaws 30 and 38. When moved in an opposite axial direction, the outer member 34 releases the jaws 30 and 38 so they open. Further description in the Yoon specification describes operation of the jaws 38 and 40 to hold or release different objects. Most importantly, the jaws manipulate a piece of anatomical tissue T. There is no teaching of a structure for handling a suture. There is no disclosure of a syringe.

The rejection states that Yoon discloses, "a syringe (84) having a needle (44) that extends through the elongated tubular member [34] towards the jaws and is capable of receiving a suture." The rejection refers to a syringe 84. It is respectfully submitted that the component 84 is not a syringe. In Figure 10 and at column 5, line 39, Yoon explains that element 84 is a valve. Yoon points out at column 5 lines 26-29 that the valve 84 permits a channel 44 to be used for irrigation or suction. Note that irrigation and suction are tasks performed by surgeons which comprise administering fluid or removing fluid respectively. Sutures do not belong in irrigation lines or suction lines. At line 28, Yoon points out that the member 42 can be coupled to an appropriate suture. A suture does not extend through the elongated tubular member 34. There is no syringe structure in Yoon. Fluid is moved by an external source of pressure applied to the valve 84. A syringe, by definition, is a pump. There is no pump disclosed in Yoon.

In claim 12 at lines 1-3, Applicant recites an elongate tubular member having a passage extending from a proximal end to a distal end. As recited at lines 7-9, the instrument further comprises a syringe having a needle of sufficient length to extend through said passage. The needle must also be capable of extending through an opening in one of first and second jaws at the distal end of the passage. The needle includes a cannula which can receive a suture, as recited at line 10. At line 11, it is recited that the syringe can draw

a suture into the needle and expel a suture through the needle. Yoon does not disclose this structure. There is no needle extending from a proximal end to a distal end of the passage. A form of needle 76 is disclosed in figure 12. This needle is not capable of extending beyond the jaws 38 and 40. There is no opening in either of the jaws 38 or 40. Therefore, there is no basis on which Yoon can form the basis for rejection under 35 U.S.C. §102(b).

#### 3. Haber

Claims 1, 8-11 and 12-14 stand rejected under 35 U.S.C. §102(b) as being anticipated by Haber in accordance with paragraph 10 of the rejection. The rejection states Haber, "discloses a syringe having a barrel (72) and a plunger (78) and a connector (24), in which the barrel is capable of receiving a suture. Further, [Haber] discloses the elongated cannulated suturing needle (40) capable of receiving a suture; and the distal end containing a sharp point (118)."

It is once again respectfully submitted that the characterization of the art is unsupported by the record. Haber does not disclose a syringe. There is no pumping mechanism. The component 40 is not a cannulated suturing needle. Such needle as disclosed by Haber can only dispense and cannot receive a suture.

There is no syringe disclosed in Haber. A syringe is a fluid pump. There is no fluid pump in Haber. The component 78 is not a plunger. A plunger, by

definition, moves axially within a cylinder. Haber identifies the components 78 as a trigger actuator. It is not mounted within a cylinder. Haber states that axial movement of trigger 78 causes pin 82 to ride along spiral groove 90, thus rotating tube 8 and tip assembly 10 therewith about axis 22. See, for example, Figures 6A and 6B. The trigger 78 does not draw in or expel a suture.

Suture material 93 is delivered from a radially extending aperture at the side of the tube. It is not delivered through a needle extending through a passage. The suture material 93 is maintained on a suture material supplies pool 89. Haber does not disclose means for drawing a free end of the suture into the apparatus. It is also noted that component 40 is not a cannulated suturing needle. The components 40 is a drive rod. Haber's apparatus does not comprise a syringe. His suturing material 93, as seen in Figure 4, for example, exits through a radially extending aperture 93. A surgeon can operate jaws 26 and 28 with Haber's apparatus. The surgeon can rotate the jaws 26 and 28 as well. However, a needle that can penetrate tissue does not extend axially from Haber's tube eight. Haber's apparatus is not suitable for capturing a free end of a suture that may be anchored to a location on the patient and drawing that suture end into the apparatus.

Haber does not include the elements specifically recited by Applicant.

For example, in claim 1, at lines 1-3, Applicant recites a syringe having a barrel

and plunger and a connector for detachably mounting a needle. Haber does not comprise a syringe or a plunger. At lines 5-19 Applicant recites a suturing needle with a connector adapted to connect the syringe barrel and a proximal end of the needle. There is no such structure in Haber.

Due to the structure expressly recited by Applicant, a suture material is propelled either in or out of the apparatus by hydrodynamic force. Haber uses mechanical engagement of components with the suture material, providing the potential for abrasion of suture material and failure that is absent with hydrodynamic propulsion. Also Haber does not disclose any means for drawing a suture material into the apparatus.

Dependent claims are also rejected on Haber. Since Haber is not anticipatory of the independent claims, it cannot anticipate dependent claims. However it is noted that the rejection of claim 8 states that Haber discloses a cover 8 over most of the needle. It is submitted that the cover 8 does not surround a needle. In any event, Haber does not disclose a needle coupled to a syringe.

With respect to the rejection of claim 9, Haber's jaws 26 and 28 are not at a distal end of a passage as defined by Applicant. In the arrangement recited by Applicant, the jaws surround a needle from which a suture may enter or exit. Haber's aperture 93 does not direct suture material between the jaws 26 and 28.

The rejection refers to an opening between the jaws 26 and 28. However, this is not what Applicant recites. Applicant recites an opening <u>in</u> a jaw. In paragraph [0038], Applicant states, "Upper jaw 48 has an opening 68 as shown in FIG. 4 for passage of a tip and portion of the outer end of a suturing needle and a suture." There is no opening in either of jaws 26 or 28. Applicant discloses an opening 68 in the jaw 48 and an opening 62 in the jaw 42, see, for example, Figure 4 and Figure 5B.

With respect to the rejection of claim 10, the needle 118 with a curved end is not connected to Haber's apparatus; it is held by the jaws 26 and 28 and manipulated by Haber's apparatus. The rejection of claim 11 states that the lumen disclosed in figure 1 is circular. Haber does not disclose the lumen as defined by Applicant.

In accordance with paragraph 16 of the rejection, independent claim 12 and claims 13 and 14 dependent thereon are also rejected under 35 U.S.C. §102(b) on Haber. Paragraph 17 of the rejection states that there is a syringe capable of holding liquid and sutures. There is no syringe in the apparatus disclosed by Haber.

With respect to the rejection of claim 13, the needle 118 with a curved end is not connected to Haber's apparatus. It is held by the jaws 26 and 28 and manipulated by Haber's apparatus. The rejection of claim 14 states that the

lumen disclosed in Figure 1 is circular. Haber does not disclose the lumen as defined by Applicant.

MPEP §2131 states, "TO ANTICIPATE A CLAIM, THE REFERENCE MUST TEACH EVERY ELEMENT OF THE CLAIM." With respect to the rejections based on each of Lüscher, Yoon and Haber, Applicant demonstrates the references do not disclose elements recited by Applicant. Therefore, it is submitted that the rejections based on 35 U.S.C. §102(b) should be withdrawn.

The Rejection Under 35 U.S.C. §103(a)

## 1. Requirements for a Rejection Under 35 U.S.C. §103(a)

Applicant incorporates his arguments above regarding 35 USC §102(b) as to respective references in the traversal of rejections under 35 U.S.C. §103(a) below. MPEP §2143.03 requires that all limitations of the claims must be taught or suggested in a rejection under 35 U.S.C. §103(a). It is submitted that essential elements of Applicant's recitations are not shown in the art of record. Further, under MPEP §2143.01, a rejection cannot be based on a combination that would render the apparatus forming the basis of an obviousness rejection unsuitable for its original purpose. Such rejection does not meet the requirement that there must be a suggestion or motivation in the art to modify the references.

### 2. Lüscher in view of Craig

Pursuant to paragraph 22 of the rejection, Claims 2-4 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Lüscher as applied to claim 1. This ground of rejection states that Lüscher teaches all the limitations of claims 2-4 except for a curved, distal end of the needle. The rejection states that Craig teaches the use of a curved, corkscrew or hook needle. Even assuming arguendo that Craig is combinable to show the feature of a curved needle, it is noted that there is no base apparatus in the combination of references corresponding to Applicant's recited structure. Therefore, it is submitted that the rejection under 35 U.S.C. §103(a) should be withdrawn.

Further, it is submitted that Craig does not provide the missing teaching of Lüscher. Applicant recites an elongated cannulated needle. In accordance with the teachings of Craig, a curved needle 11 is provided which is solid. A possibly elongated and a cannulated needle 19 is provided which is separate. In the embodiment of figure 4, Craig discloses a hollow needle. However, whether or not Craig provides a teaching applicable to an elongated cannulated needle, no basis for a rejection under 35 U.S.C. §103(a) is present as the combination of references fails to teach the claimed features.

## 3. Lüscher in view of Sontag

In paragraph 25 of the rejection, Claim 5 is rejected under 35 U.S.C. §103(a) as being unpatentable over Lüscher as applied to claim 1 in view of Sontag. The rejection states that Lüscher teaches the limitations of claim 5 except for a rounded tip of a suture needle. Sontag teaches a suturing needle with openings at the end that are slightly rounded to protect the surgeon from accidental cuts or punctures. It would have been obvious to use rounded needles in order to protect the user from accidental cuts. It is respectfully submitted that these grounds of rejection do not address the recitations of the claims.

Claim 5 recites an embodiment wherein an opening at a distal end of a needle is at a side of a cannula and wherein a trailing edge of the opening is rounded. In order to provide a teaching relevant to claim 5, there must be an aperture with a leading edge and a trailing edge. Sontag has no such disclosure. His opening (and Applicant does not concede that the opening is in a cannula) is at an end of a needle. There is no leading edge and no trailing edge. Applicant recites that the trailing edge is rounded. Since Sontag does not recognize that there is a leading edge or a trailing edge, Sontag cannot teach that it is necessary to round a trailing edge while not necessarily rounding other images.

Applicant does not require that the leading edge be rounded. A user can be cut by a sharp leading edge or a sharp trailing edge. Therefore, Sontag's motivation of protecting a user from being cut is irrelevant to arriving at Applicant's recited structure. As pointed out in §MPEP 2143.01, prior art that gives motivation based on one principle of operation does not provide a teaching that renders obvious a method or apparatus not using that principle.

Applicant's unique structure provides a means for drawing in a loose end of a suture and later expelling it. The art of record does not teach this. Once the loose end of the suture is drawn into the needle, the suture is carried by the needlepoint through tissue. As shown by Applicant, for example with respect to Figure 12, when the suture end is traveling through tissue, the suture is compressed between the tissue and the trailing edge of the aperture. Pressure is applied against the suture, and a force could be applied to the suture by the trailing edge which would tend to cut the suture. Therefore, in one form, Applicant assures that the trailing edge is rounded. The art of record has no reason to consider the formation of the trailing edge since there is no disclosure of taking a loose end of the suture and putting it into a needle in directing the suture toward a chamber in a syringe. Since the prior art has no recognition of performing this function, it cannot provide motivation for ways of performing the function.

It is therefore submitted that this round of rejection under 35 U.S.C. §103(a) should be withdrawn.

#### 4. Lüscher and Sontag further in view of Craig

Paragraph 28 of the rejection states that Claims 6 and 7 are rejected under 35 U.S.C. §103(a) as being unpatentable over Lüscher and Sontag further in view of Craig. This rejection takes the position that Lüscher and Sontag each teach the limitations except for the use of a curved needle and that the use of a curved needle is obvious because a curved needle is more efficient. Even assuming arguendo that Craig is combinable to show the feature of a curved needle, there is no base apparatus corresponding to Applicant's recited structure with which to combine a reference. Therefore, it is submitted that the rejection under 35 U.S.C. §103(a) should be withdrawn.

Further, it is submitted that Craig does not provide the missing teaching of the other references. Applicant recites an elongated cannulated needle. In accordance with the teachings of Craig, a curved needle 11 is provided which is solid. A possibly elongated and a cannulated needle 19 is provided which is separate. In the embodiment of figure 4, Craig discloses a hollow needle. However, whether or not Craig provides a teaching applicable to an elongated cannulated needle, no basis for a rejection under 35 U.S.C. §103(a) is present.

### 5. Weng and Lüscher

Pursuant to paragraph 31 of the rejection, Claims 15, 16 and 18 stand rejected under 35 U.S.C. §103(a) as being unpatentable over United States Patent No. 5,569,270 to Weng and Lüscher. The rejection states that Weng teaches a method of suturing which includes providing an elongated needle 46 having a lumen extending from the proximal end to the distal end that is capable of passing a suture. Suture material is introduced into the needle. Liquid fills a syringe and needle is passed through the tissue, the suture being expelled with the force of liquid flow. The rejection further states that Lüscher teaches a syringe for expelling the liquid.

Independent claim 15 recites a method in which a suture is introduced into a syringe and liquid is provided in the syringe, lines 6 and 7. A distal end of the needle is passed with the suture through a tissue, lines 7 and 8. After the suture passes through the tissue, liquid is expelled from the syringe and the suture is expelled from the needle, lines 8-10.

It submitted that any issue as to this rejection is avoided by the amendment of claim 15. Claim 15 recites that introducing suture material into the syringe comprises introducing the suture material from outside of the apparatus being utilized. As explained above, Lüscher contains a spool of non-suture material inside the apparatus. Weng also provides a spool within the

apparatus, Weng's spool carrying suture material. The cited art does not provide for introducing suture material from outside of the apparatus. It should also be noted that Lüscher does teach expelling liquid from a syringe. However, Lüscher makes no teaching of drawing liquid or suture material or his non-suture material into a needle.

Claim 15 as amended further explicitly recites that a portion of the suture material is outside the needle when the needle passes through a patient's tissue. This recitation is expressly contrary to the teachings of the art of record. It is therefore submitted that the issue of obviousness is avoided and that the rejection under 35 U.S.C. §103(a) should be withdrawn.

Additionally, claim 16 as filed includes express recitations neither shown nor suggested in the prior art. At claim 16, line 3, Applicant recites inserting an end of the suture into a distal of a needle. The art of record only discloses expelling a suture from a distal end of the needle. The suture is inserted at a proximal end of the needle. Since the prior art does not include the limitations recited in Applicant's claims, a rejection under 35 U.S.C. §103(a) cannot be made out. It is therefore submitted that this ground of rejection should be withdrawn.

#### 6. Weng and Lüscher in view of Craig

Claim 17 is rejected under 35 U.S.C. §103(a) as being unpatentable over Weng and Lüscher as applied to claim 16 in view of Craig. The rejection states that Weng and Lüscher teach the limitations of claim 17 except for the use of a curved needle.

Even if Craig were to be combinable with Weng or Lüscher, the limitations of the method of claim 15 are not found in the art. Under MPEP §2143.03, all limitations must be found in the combined art to meet a claim in an obviousness rejection. The limitation of drawing a suture into the apparatus from outside the apparatus is not suggested in the prior art. No motivation is provided. Therefore, withdrawal of the rejection is warranted. Additionally, it cannot be assumed that Craig is readily combinable with Weng or Lüscher. Therefore, this ground of rejection merits withdrawal.

# 7. Weng and Lüscher and Sontag in view of Haber

In paragraph 37 of the rejection, Claims 19 and 20 are rejected as being unpatentable over Weng and Lüscher as applied to claim 15 in view of Haber. The rejection states that Haber teaches an elongated tubular member having a distal and proximal end, a pair of first and second jaws 26 and 28 movable relative to another with handles 16 and 18 and also includes a needle 40 capable of going through a passage to jaws, wherein a syringe is capable of

holding fluid and sutures. The method includes grasping tissue in order to suture it. The rejection further states that it would have been obvious to one skilled in the art at the time the invention was made to combine the device taught by Weng and Lüscher with the forceps taught by Haber because of forceps allow the user to grasp tissue while suturing it. It is respectfully submitted that this rejection does not address the recitations of claims 19 and 20 and also that the characterizations of the art are unsupported by the record.

At claim 19, lines 5-7, elements of Applicant's environment in which the method is performed are recited. First and second jaws each having an opening therethrough at the end of a passage are recited. Applicant specifically recites individual jaws having an opening therethrough. Such an opening is illustrated, for example, in Figure 12. The jaws in the art of record are solid. At lines 10 and 11, claim 19 recites that the jaws can grasp a tissue to be sutured. At lines 11-13, claim 19 recites that a distal end of a needle passes through an opening in a jaw and through the tissue. This is illustrated, for example, in Figure 4. In paragraph [0038], Applicant states, "Upper jaw 48 has an opening 68 as shown in FIG. 4 for passage of a tip and portion of the outer end of a suturing needle and a suture." Applicant explicitly recites that a needle goes through the jaws while tissue is being grasped, i.e., while the jaws are closed. In the art of record, it is impossible to place an object through closed jaws. Since it is impossible to perform the explicit function recited by Applicant, the art of record can not serve

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to render Applicant's claims obvious. It is therefore submitted that this ground of rejection should be withdrawn.

#### Summary

Applicant provides for operational advantages through the recited method and apparatus. One function that can be performed is the capture of a free end of the suture to a patient location, for example. Applicant explicitly recites structure in the apparatus claims and steps in the method claims which provide for performance of unique functions. Applicant has distinguished on his recitations from the part of record as explained in detail above. Since the order record does not disclose all of the limitations recited by Applicant, it is submitted that the requirements of the MPEP for a rejection under either 35 U.S.C. §102(b) or 35 U.S.C. §103(a) have not been met.

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Applicant therefore respectfully submits that the application is now in condition for allowance. If it is believed that the application is not in condition for allowance, the Examiner is respectfully requested to contact the undersigned to expedite the prosecution of the application.

Respectfully submitted,

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